

Veterans Walk for Health Subject Checklist



Site #: 2

Line #:

VISIT 1 (ENROLLMENT)

Date: / /

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
1.1	Add Name and SSN to <i>Crosswalk 2</i> (SC)	
1.2.	Document height/ weight and BMI. (SC) <ul style="list-style-type: none"> Record in CPRS Cover Sheet Record on <i>Screening for Eligibility Worksheet</i>. Record which scale was used (this scale is to be used for this patient at each subsequent study visit) 	
1.3. (1.5,1.7)	Introduce study to patient (SC) <ul style="list-style-type: none"> Stress that he has a choice to participate. Dispense <i>Recruitment Flyer</i> Discuss study briefly using <i>Recruitment Flyer</i>, <i>3 cards</i>, and pedometer devices as visual aids (If <u>not interested</u>, ask patient if he will let us know why so that we can use the information when planning studies in the future, and document on <i>Crosswalk 1</i>. Make sure patient leaves with an appointment scheduled for a regular nutritional counseling session and an appointment card. Record information from <i>Crosswalk 1</i> and <i>Screening for Eligibility Worksheet</i> in Survey Monkey.) 	
1.6. (1.7)	Check Eligibility (SC) <ul style="list-style-type: none"> Complete <i>Screening for Eligibility Worksheet</i> (If <u>not eligible</u> record the reason on <i>Crosswalk 1</i>. Make sure the patient leaves with an appointment scheduled for a regular nutritional counseling session and with an appointment card. Record information from <i>Crosswalk 1</i> and <i>Screening for Eligibility Worksheet</i> in Survey Monkey.) 	
1.9.1 (1.5,1.7)	Consent Patient (SC) <ul style="list-style-type: none"> Dispense <i>Consent Form</i>. Explain major points to patient and then allow him to read it on his own, or read in its entirety to patient if he prefers. Have patient initial each page to document he has seen it. Make sure that all of the patient's questions have been answered, and that consent is fully informed. If the patient consents, have him sign and date the <i>consent form</i> (including the authorization form.) Have witness sign (competent adult not affiliated with the research group.) Sign as the person obtaining consent. Check to be sure all pages are initialed, required signatures are present, and dates are correct. Highlight the study staff contact information for the participant. Add the consent date and consent version to <i>Crosswalk 1</i>. (If <u>not interested</u>, ask patient if he will let us know why so that we can use the information when planning studies in the future, and document on <i>Crosswalk 1</i>. Make sure the patient leaves with an appointment scheduled for a regular nutritional counseling session and with an appointment card. Record information from <i>Crosswalk 1</i> and <i>Screening for Eligibility Worksheet</i> in Survey Monkey.) 	
1.8	Give a Copy of the <i>Consent Form</i> to the participant (SC) <ul style="list-style-type: none"> Make a copy of the <i>Consent Form</i> for the participant to take home today (or have him initial/sign/date two identical copies, one for the study site and one to take home.) Hold on the original (further instructions at the end of Visit 1.) Dispense pamphlet "I'm a Veteran Should I Participate in Research." 	

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1.9.2	Participant completes top of <i>Medical Clearance Form</i> (SC) <ul style="list-style-type: none"> Explain that before the next study visit you will ask the participant's physician if it is safe for him to start walking. Add patient name and SSN to form. 	
1.9.3	Assign Enrollment ID using <i>Crosswalk 1</i> (SC) <ul style="list-style-type: none"> Ask participant for an alternate contact person and phone number in case we can't reach him at home. Record on <i>Crosswalk 2</i>. 	
1.15	Distribute Actical (SC) <ul style="list-style-type: none"> Record enrollment ID and date dispensed on the <i>Actical Log</i> for the serial # dispensed. Set up Actical on Actireader and write user identity (Enrol. ID and V#), start date and time, and participants ht/wt. Make sure the battery life extends beyond the date the participant is to wear the Actical. Explain that it measures activity level, and we are looking to get an idea of how active they are before starting the new walking program, so we want them to do whatever it is that they have been doing. Demonstrate how to wear it (arrow up). Dispense <i>Actical Use</i> Handout. Record dates that the device will be worn on the <i>Actical Wearing Log</i>. Dispense the log to the participant and explain how to complete it. Instruct participant to wear the Actical each day (off only at night) for a full seven days. Time Actical put on the participant: _____:_____ am pm 	
1.16	Administer <i>Baseline Survey</i> (SC) <ul style="list-style-type: none"> Add Enrollment ID to top of <i>Baseline Survey</i>. Let participant know that it will take ~20-30 min. to complete, that he does not have to complete anything that he doesn't feel comfortable completing, and that he can ask you if he has questions. Ask if the participant would like to complete the survey independently or if he would like you to read it to him. Review any skipped answers with participant to make sure they were skipped intentionally and not as an oversight. Add Baseline Survey date to <i>Crosswalk 1</i>. 	
1.18.	Schedule Visit 2 (SC) <ul style="list-style-type: none"> There must be seven full days of Actical data, so this appointment needs to be scheduled at least 7 days from today and at the time of day the Actical was put on or later. This visit can be up to 14 days after Visit 1. Have planner available, document appointment. Give participant appointment card. Confirm participant's telephone number (for reminder call) and record on <i>Crosswalk 2</i>. 	
1.18	Give participant phone card (SC) <ul style="list-style-type: none"> Complete <i>Payment Record/Receipt</i> and have the participant sign and date. 	
1.17	Have participant's MD sign <i>Medical Clearance Form</i> (SC) <ul style="list-style-type: none"> Label with participant name and last 4 of SSN Keep original locked in Medical Clearance File 	
1.20	SOC from Baseline Survey (SC) <ul style="list-style-type: none"> Make a copy of pages 4-7 of the <i>Baseline Survey</i> and label it with patient name and last four digits of the SSN. Put this in a yellow visit 2 file (give to the RD at visit 2). 	

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	Document the informed consent process <ul style="list-style-type: none"> Complete CPRS template "Documentation of Informed Consent discussion for Research Study." 	
1.20	<i>Consent Form Filing (SC)</i> <ul style="list-style-type: none"> Obtain site PI signature. Send copy to IRB Office (it will be sent to MAS and scanned to CPRS). Lock original in Consent Form File. 	
1.20	<i>Screening for Eligibility Worksheet (SC)</i> <ul style="list-style-type: none"> File in a yellow visit 2 file with SOC from <i>Baseline Survey</i>. Enter data from this form and from the <i>Crosswalk 1</i> and <i>Crosswalk 2</i> into Survey Monkey. 	
1.20	<i>Baseline Survey (SC)</i> <ul style="list-style-type: none"> Enter survey into Survey Monkey. Send original to Ann Arbor in monthly shipment. 	
1.21	Reminder call to participant before next study visit (SC) <ul style="list-style-type: none"> Date of reminder call: ____/____/____ Confirm with participant that he will have worn the Actical for at least seven full days as of the time of next appointment. Remind participant to bring Actical and <i>Actical Wearing Log</i> to visit. 	